

REMARKS

Applicant respectfully requests reconsideration. Claims 1-13 were previously pending in this application. Claim 13 is withdrawn. Claims 1, 6 and 12 have been amended. No claims have been added or cancelled. As a result, claims 1-12 are pending for examination with claims 1 and 6 being independent claims. No new matter has been added.

Submitted with this Amendment is an additional document entitled: "Declaration under 37 CFR 1.132 of Dr. Alejandro Balazs," referred to as Declaration.

Rejections Under 35 U.S.C. §102

Claims 1-3, 5-8, 10, and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by Ghannadan et al., (Int. Arch Allergy Immunol. 127: 299-307, 2002). The Examiner states that "Ghannadan teaches identical method steps as instantly claimed and the source of the biological sample as instantly claimed is broad and is not limited to any source thus the HMC-1 as a source of a biological sample anticipates the claimed invention" (page 4 of the Office Action). Applicant respectfully disagrees and traverses the rejection. Discussion of the rejection follows and is supported by and includes reference to the Declaration under 37 CFR 1.132 of Dr. Alejandro Balazs. As evident from his Declaration, Dr. Balazs disagrees with the Examiner's conclusion that Ghannadan et al. anticipates the instant invention. Further, as stated by Dr. Balazs in his Declaration and clarified below, the Examiner has relied upon an incorrect interpretation of the teachings of the cited reference to make the 102 rejection.

Without conceding the correctness of the rejection, and solely to expedite prosecution, Applicant has amended claims 1 and 6 to recite "a biological sample comprising a mixture of cells" and claim 12 has been amended to depend on claim 1. Support for this amendment can be found, for example, on page 3, line 23 of the application as filed. The HMC-1 cell line of Ghannadan et al. is a homogeneous population of cells with the properties of naturally occurring immature mast cells, and is not a mixture of cells. This cell line does not contain hematopoietic stem cells and cannot be separated into hematopoietic stem cells or selected from to obtain hematopoietic stem cells. Accordingly, the claims as amended are not anticipated by Ghannadan et al.

MPEP § 2131 states that “‘A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.’ Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).” The inventors of the instant application have demonstrated that it is possible to produce a substantially pure population of hematopoietic stem cells from a mixture of cells using a single EPCR marker. Ghannadan et al. does not teach a method for obtaining a substantially pure population of hematopoietic stem cells as instantly claimed. Instead, Ghannadan et al. teaches that mast cells and basophils express a unique combination of surface antigens and that novel CD antibodies may help to isolate mast cells and basophils (Abstract and page 306, second column; emphasis added).

Even if one of skill in the art were to contact the HMC-1 cell line with an affinity agent for EPCR, followed by separation of the cells, the result cannot be a substantially pure population of hematopoietic stem cells. As stated by Dr. Balazs in his Declaration, “[t]he HMC-1 cell line, which is a mast cell line does not contain any hematopoietic stem cells and, therefore, is not possible to obtain hematopoietic stem cells using HMC-1 and an endothelial cell C protein antibody. Mast cells are highly specialized cells found in tissues throughout the body and play a role in allergy and anaphylaxis. Unlike hematopoietic stem cells, mast cells do not have the capacity to reconstitute the entire hematopoietic system. The mast cell line cannot produce nor does it contain any hematopoietic stem cells. Therefore it would not have been possible to obtain hematopoietic stem cells using HMC-1 and an endothelial cell C protein antibody” (Item 3).

Thus, in summary, Ghannadan et al. does not disclose a method by which a substantially pure population of hematopoietic stem cells can be obtained and it cannot anticipate the pending claims.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 1-3, 4, 5-8, 9, 10, 11, and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ghannadan et al (Int Arch Allergy Immunol. 127: 299-307, 2002) in view of Goodell et al, (J Exp Med, 183: 1797-1806, 199).

The Examiner alleges that “it would have been obvious to the ordinarily skilled artisan to modify the teachings of Ghannadan et al, by utilizing the Hoechst 33342 dye exclusion technology of Goodell in order to obtain a pure enriched population of EPCR+ cells in a murine biological sample” (page 7 of the Office Action). Applicant respectfully disagrees and traverses the rejection.

The teachings and deficiencies of Ghannadan et al. have been discussed in response to the previous § 102 rejection. Ghannadan et al. does not disclose a method by which a population of hematopoietic stem cells can be obtained. HMC-1 is an immature mast cell line and it would not have been possible to obtain any hematopoietic stem cells. It also would not have been possible (or obvious) to obtain substantially pure populations of hematopoietic stem cells.

Goodell et al. does not cure the deficiencies of Ghannadan et al. Even if a skilled artisan had combined the teachings of Ghannadan et al. and Goodell et al., it would not have been possible to obtain hematopoietic stem cells, which are not produced by the HMC-1 cell line and, thus, cannot be obtained. Therefore, the combined references cannot render obvious the claimed invention; the combination of cited references does not yield all the limitations of the claimed invention.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-3, 5-8, 10, and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ghannadan et al., (Int Arch Allergy Immunol, 127: 299-307, 2002) in view of Miyazato et al., (Blood, 98: 422-427, 2001).

The Examiner alleges that “it would have been obvious to the ordinarily skilled artisan to modify the teachings of Ghannadan et al. by utilizing column chromatography in order to obtain enriched population of EPCR+ cells in a biological sample as taught by Miyazato et al. with a reasonable expectation of success” (page 7 of the Office Action). Applicant respectfully disagrees and traverses the rejection.

The teachings and deficiencies of Ghannadan et al. have been discussed in response to the previous § 102 rejection. Ghannadan et al. does not disclose a method by which a population of hematopoietic stem cells can be obtained. It would not have been possible to obtain hematopoietic

stem cells or substantially pure populations of hematopoietic stem cells using the cell line HMC-1, which is an immature mast cell line.

Miyazato et al. does not cure the deficiencies of Ghannadan et al. Even if a skilled artisan had combined the teachings of Ghannadan et al. and Miyazato et al., it would not have been possible to obtain hematopoietic stem cells, in view of the fact that the cell line used by Ghannadan et al. does not produce hematopoietic stem cells. The combined references do not render obvious the claimed invention, at least because the combination of cited references cannot yield all the limitations of the claimed invention.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1233.70001US01.

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Respectfully submitted,

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